

JUN 17 2004

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
in Accordance with SMDA of 1990

K040864

**CRANIOFIX TITANIUM CLAMP SYSTEM**

April 1, 2004

**COMPANY:** Aesculap®, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034

**CONTACT:** Kathy A. Racosky, Regulatory Affairs Associate  
800-258-1946 (phone)  
610-231-3713 (fax)  
[kathy.racosky@aesclap.com](mailto:kathy.racosky@aesclap.com) (email)

**TRADE NAME:** CranioFix and CranioFix2 Titanium Clamp System

**COMMON NAME:** Cranioplasty Plate Fastener (Burr Hole Cover)

**DEVICE CLASS:** CLASS II

PRODUCT CODE	DEVICE	CLASSIFICATION	REVIEW PANEL
84HBW	Fastener,Plate, Cranioplasty	882.5360	84 Neurology
84GXR	Cover, Burr Hole	882.5250	84 Neurology
76JEY	Plate, Bone	872.4760	76 Dental
84GXN	Plate,Cranioplasty, Preformed, Non-Altered	882.5330	84 Neurology

**INTENDED USE**

Aesculap's CranioFix and CranioFix2 System are intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

**DEVICE DESCRIPTION**

The CranioFix and CranioFix2 Clamp System consist of sterile, titanium implants (Clamps) and associated manual instruments. The Clamps are available in three sizes: 11mm, 16mm, and 20mm. The clamp consists of two concave disks which are connected with a pin through the center. The pin is securely attached to the lower disk; the upper disk is loosely mounted onto the pin. Each disk has rows of teeth extending along the edge of the concave side. The disks are mounted onto the pin with the teeth of each one facing the teeth of the other. The disks of the CranioFix Titanium Clamp (11mm) are solid (no drainage holes). The disks of the CranioFix Titanium Clamp (16mm and 20mm) have open areas for drainage. The CranioFix2 Titanium Clamp (11mm, 16mm, and 20mm) have a sleeve securely attached on the end of the pin. During the fixation, the lower disk comes to rest against the inner surface of the cranium and the upper disk comes to rest against the outer surface of the cranium.

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**PURPOSE FOR SUBMISSION**

The purpose for this submission is to gain marketing clearance for additions to Aesculap's CranioFix Clamp System and the expansion to the indication for use statement for Aesculap's Titanium CranioFix Clamp System.

**PERFORMANCE DATA**

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

**SUBSTANTIAL EQUIVALENCE**

The device modifications and expanded indications for use described in this premarket notification are substantially equivalent to these predicate devices:

- Aesculap CranioFix Titanium Clamp System (K972332)
- Aesculap Craniofacial Implant Set (K923705)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 17 2004

Kathy A. Racosky  
Regulatory Affairs Associate  
Aesculap, Inc.  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K040864

Trade/Device Name: CranioFix Titanium Clamp System  
Regulation Number: 21 CFR 882.5330  
Regulation Name: Preformed nonalterable cranioplasty plate  
Regulatory Class: II  
Product Code: GXN  
Dated: April 1, 2004  
Received: April 2, 2004

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

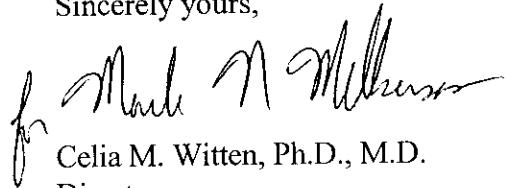
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Kathy A. Racosky

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K040864

Device Name: CranoFix Titanium Clamp System

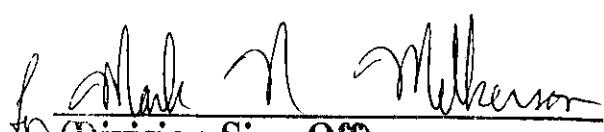
**Indication for Use:**

Aesculap's CranoFix and CranoFix2 System are intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

Prescription Use X or Over-the-Counter Use \_\_\_\_\_

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K040864